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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/448,633	11/24/1999	AI-PING WEI	53091USA8B	5266

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EXAMINER

MORAN, MARJORIE A

ART UNIT PAPER NUMBER

1631

DATE MAILED: 06/03/2002

B

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/448,633	Applicant(s) WEI ET AL.	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-19 and 21 is/are rejected.
- 7) ☒ Claim(s) 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>12</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 1-2 and 4-21 are pending.

Information Disclosure Statement

Applicant is thanked for providing a new copy of the IDS originally filed 2/29/00. The IDS has been considered in full.

Claim Rejections - 35 USC § 102

Claims 1, 4, 6-8, 10, 12-13, and 15-18 are again rejected, as previously set forth in the office action of 12/4/01, under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over GARMAN *et al.* (GB 2278356) with support from ROHATGI *et al.* (J. Phys. Chem. (6/1966) vol. 70 (6), pages 1695-1701), WEI *et al.* (Anal. Chem. (5/1994), vol. 66 (9), pages 1500-1506), and TSIEN *et al.* (US 5,741,657).

Applicant's arguments filed 3/12/02 have been fully considered but they are not persuasive. In response to the argument and reference to Ex Parte Skinner, apparently in support of the argument, that the Examiner has not "met the burden" of providing evidence or sound scientific reasoning to establish that the functional limitation (i.e. dimerization) is an inherent characteristic of the prior art, the examiner maintains that the teachings of GARMAN, ROHATGI, WEI and TSIEN do provide evidence that fluorescein and tetramethylrhodamine (TMR) are capable of dye-stacking such that, using sound scientific reasoning, one skilled in the art would reasonably conclude that the fluorescein and TMR attached to GARMAN's enzyme substrate inherently undergo dye-stacking in an aqueous (polar) buffer. Applicant contends that the substrates of GARMAN cannot, "by definition", dimerize, but fails to define what "definition"

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he if referring to; nor does applicant provide any evidence to refute the teachings of the prior art of record that fluorescein and TMR can, indeed, dimerize.

In response to applicant's references to various court cases in support of the argument that an inherent property must necessarily be present or must be a natural result of an operation as taught, it is noted that products of identical chemical composition can not have mutually exclusive properties. See *In re Papesch*, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) (a chemical compound and its properties are inseparable). As the substrate taught by GARMAN meets all of the limitations of the rejected claims, and the dye groups taught by GARMAN are among those specifically recited in dependent claims 7-8 and 17-18, the examiner maintains that the structure taught by GARMAN is identical to that recited in the instant claims, and therefore inherently comprises the properties claimed.

Applicant's attention is directed to *In re Spada* (15 USPQ2d at 1657 and 1658, decided 8/10/1990), wherein arguments similar to applicant's were made with regard to inherent properties of a product. In that case, Spada argued that Smith (the prior art) does not describe Spada's claimed invention, for to find anticipation "all limitations in the claims must be found in the reference since the claims measure the invention." In

re Lange, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Spada argued that since the Smith products are disclosed as having properties different from those of his claims, they are ipso facto different. In response, the Board stated that, "(t)he discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition. 4 *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780, 782, 227 USPQ 773, 777-78, (Fed. Cir. 1985); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974); *In re Lemin*, 326 F.2d 437,

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440, 140 USPQ 273, 276 (CCPA 1964). Thus, the initial inquiry is to the novelty of the composition. *Titanium Metals*, 778 F.2d at 780, 227 USPQ at 777. "

With regard to evidence and sound scientific reasoning, the Board found in the Spada case that

"In response to the PTO's asserted prima facie case the applicant may argue that the inference of lack of novelty was not properly drawn, for example if the PTO did not correctly apply or understand the subject matter of the reference, or if the PTO drew unwarranted conclusions therefrom. However, when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. In *re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 138 (Fed. Cir. 1986); In *re Ludtke*, 441 F.2d 660, 664, 169 USPQ 563, 566 (CCPA 1971). Spada offered no such showing. "

In the instant case, the applicant has offered no showing or evidence that GARMAN's product is not the same as that recited in the rejected claims.

The Board also found that "(a)lthough newly discovered properties can be the basis of claims to novel polymers, *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1435, 7 USPQ2d 1129, 1133 (Fed. Cir.), cert. denied, 109 S.Ct. 542 (1988), Spada did not overcome, with argument or evidence, the apparent chemical identity of his polymers and those of Smith. Spada showed no error, in science or in law, in the Board's holding that the products appeared to be the same and thus that Spada's products were not new. As we observed supra, discovery of an unobvious property and use does not overcome the statutory restraint of section 102 when the claimed composition is known. While Spada's position is that his polymers are not anticipated by the polymers of Smith because their properties are different,

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Spada was reasonably required to show that his polymer compositions are different from those described by Smith. This burden was not met by simply including the assertedly different properties in the claims. When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art."

In the instant case, as previously stated on page 5 the office action of 12/4/01, applicant has not provided any evidence that the fluorescent groups attached to the peptide substrate of GARMAN would NOT inherently dye-stack, or dimerize, under the conditions taught by GARMAN; i.e. applicant has not shown or provided evidence that his claimed structure is different from that taught by GARMAN. Given that the structure taught by GARMAN meets all of the structural limitations of the instant claims, as set forth above, and that the prior art provides support that the fluorescent groups taught by GARMAN are capable of dimerizing under the conditions taught by GARMAN, and given that applicant has not presented evidence refuting the teachings of the prior art, nor shown that the structure of GARMAN does NOT comprise the claimed properties, the examiner maintains that GARMAN anticipates the claims, and the rejection is maintained.

Claim Rejections - 35 USC § 103

Claims 1-2, 4-8 and 10-18 are again rejected, as previously set forth in the office action of 12/4/01, under 35 U.S.C. 103(a) as being unpatentable over GARMAN *et al.* (GB 2278356) as supported by ROHATGI *et al.* (J. Phys. Chem. (6/1966) vol. 70 (6), pages 1695-1701), WEI *et al.* (Anal. Chem. (5/1994), vol. 66 (9), pages 1500-1506), and TSIEN *et al.* (US 5,741,657), and in view of KOMORIYA *et al.* (US 5,714,342).

Claims 9 and 19 are again rejected, as previously set forth in the office action of 12/4/01, under 35 U.S.C. 103(a) as being unpatentable over GARMAN *et al.* (GB 2278356) as supported by ROHATGI *et al.* (J. Phys. Chem. (6/1966) vol. 70 (6), pages 1695-1701), WEI *et al.* (Anal. Chem. (5/1994), vol. 66 (9), pages 1500-1506) and TSIEN *et al.* (US 5,741,657) in view of KOMORIYA *et al.* (US 5,714,342), as applied to claims 1-8 and 10-18 above, and further in view of HEATH, JR. *et al.* (US 5,235,039).

Claim 21 is again rejected, as previously set forth in the office action of 12/4/01, under 35 U.S.C. 103(a) as being unpatentable over GARMAN *et al.* (GB 2278356) as supported by ROHATGI *et al.* (J. Phys. Chem. (6/1966) vol. 70 (6), pages 1695-1701), WEI *et al.* (Anal. Chem. (5/1994), vol. 66 (9), pages 1500-1506), and TSIEN *et al.* (US 5,741,657), and in view of MANAFI *et al.* (Microbiol. Reviews (9/1991), vol. 55 (3), pages 335-348).

Applicant's arguments filed 3/12/02 have been fully considered but they are not persuasive. Applicant repeatedly argues that GARMAN does not teach dimerization, therefore there was no motivation to combine GARMAN with any of the other references set forth in the rejections above. The examiner maintains that GARMAN teaches dimerizing dyes, as set forth above, and therefore maintains that it would have been obvious to have combined the teachings of GARMAN with the other references for the reasons and motivations previously set forth.

Allowable Subject Matter

Claim 20 is again objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:
The prior art does not teach the structure recited in claim 20. The prior art does not teach any

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motivation to pick the particular amino acid sequence recited in claim 20 as the peptide portion of the claimed substrate, nor does the prior art teach the claimed sequence as part of any other (e.g. larger) protease substrate, therefore claim 20 is not suggested by the prior art.

Conclusion

Claims 1-2, 4-19 and 21 are rejected; claim 20 is objected to.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

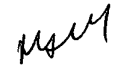
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

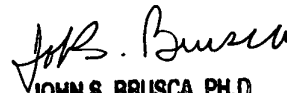
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.



Marjorie A. Moran
Examiner
Art Unit 1631

May 30, 2002



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER